APR 2 2 2014

TOBHIBA AMERICA MEDICAL BYSTEMS, INC.

2441 Michelle Drive, Tustin, CA 92780 Phone: (714) 730-5000

510(k) SUMMARY

1. SUBMITTER'S NAME:

Toshiba America Medical Systems, Inc.

2. ADDRESS:

2441 Michelle Drive Tustin, CA. 92780-2068

3. ESTABLISHMENT REGISTRATION:

2020563

4. CONTACT PERSON:

Mr. Charlemagne Chua Manager, Regulatory Affairs (714) 669-7896

5. Date Prepared:

December 6, 2013

6. TRADE NAME(S):

Diagnostic Ultrasound System Aplio 500 Model TUS-A500 V4.0 Aplio 400 Model TUS-A400 V4.0 Aplio 300 Model TUS-A300 V4.0

7. COMMON NAME:

System, Diagnostic Ultrasound

8. DEVICE CLASSIFICATION:

Class II

Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [per 21 CFR 892.1550] Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [per 21 CFR 892.1560] Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [per 21 CFR 892.1570]

9. PREDICATE DEVICE:

Product	Marketed by	510(k) Number	Clearance Date
Aplio 500/400/300 Diagnostic Ultrasound System	Toshiba America Medical Systems	K123992	February 6,2013

10. REASON FOR SUBMISSION:

Modification of a cleared device

11. DEVICE DESCRIPTION:

The Aplio 500 Model TUS-A500, Aplio 400 Model TUS-A400 and Aplio 300 Model TUS-A300 are mobile diagnostic ultrasound systems. These systems are Track 3 devices that employ a wide array of probes including flat linear array, convex linear array, and sector array with frequency ranges between approximately 2 MHz to 12 MHz.

12. INDICATIONS FOR USE:

The Diagnostic Ultrasound System Aplio 500 Model TUS-A500, Aplio 400 Model TUS-A400 and Aplio 300 Model TUS-A300 is indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intra-operative (abdominal), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, and musculo-skeletal (both conventional and superficial).

13. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the Aplio 500/400/300 V3.0 Diagnostic Ultrasound System, 510(k) cleared under K123992, marketed by Toshiba America Medical Systems. The Aplio 500 Model TUS-A500 Version 4.0, Aplio 400 Model TUS-A400 Version 4.0 and Aplio 300 Model TUS-A300 Version 4.0, functions in a manner similar to and is intended for the same use as the predicate device. The subject device includes modifications to the cleared device which improves upon existing features including the image visualization of blood flow. A comparison table is included in this submission detailing the similarities and differences between the predicate device and the subject device.

14. SAFETY:

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37, IEC 62304, NEMA UD3 Output Display and ISO 10993-1 standards.

15. TESTING

Risk Analysis, Verification/Validation testing conducted through bench testing and the acquisition of representative clinical images included in this submission demonstrate that the requirements for the improved/added features have been met.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

Additionally, testing of the modified system was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices.

16. CONCLUSION

The modifications incorporated into the Aplio 500 Model TUS-A500 Version 4.0, Aplio 400 Model TUS-A400 Version 4.0 and Aplio 300 Model TUS-A300 Version 4.0 do not change the indications for use or the intended use of the device. Based upon bench testing, acquisition of representative clinical images, successful completion of software validation, application of risk management and design controls, it is concluded that this device is safe and effective for its intended use.



Food and Drug Administration 10903 New Hampshire Avenue Document Control Center – WO66-G609 Silver Spring, MD 20993-0002

April 22, 2014

Toshiba Medical Systems Corporation Paul Biggins 2441 Michelle Drive TUSTIN CA 92780

Re: K133761

Trade/Device Name: Aplio 500/400/300 Diagnostic Ultrasound System V4.0

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: March 20, 2014 Received: March 21, 2014

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Aplio 55/400/300 Diagnostic Ultrasound System V4.0, as described in your premarket notification:

Transducer Model Number

PST-25BT	PST-30BT	PST-50BT	PST-65AT
PVT-375BT	PVT-375MV	PVT-382BT	PVT-382MV
PVT-661VT	PVT-781VT	PVT-674BT	PVT-675MV
PVT-681MV	PVT-712BT	PVT-745BTF	PVT-745BTH
PVT-745BTV	PVT-770RT	PLT-604AT	PLT-704AT
PLT-704SBT	PLT-705BTF	PVT-705BTH	PLT-805AT
PLT-1005BT	PLT-1202S	PLT-1204BT	PLT-1204BX
PLT-1204MV	PET-508MA	PET-510MB	PET-512MC
	PC-20M	PC-50M	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below.

510(k) Number (if known)	
K133761	
Device Name	
Aplio 500/400/300 V4.0 Diagnostic Ultrasound S	System
Indications for Use (Describe)	
The Diagnostic Ultrasound System Aplio 500 Mod Aplio 300 Model TUS-A300 is indicated for the processes with the human body using ultrasound diagnosis in the following clinical application (abdominal), pediatric, small organs, trans-valued adult cephalic, cardiac (both adult and pediate and musculo-skeletal (both conventional and su	visualization of structures, and dynamic and to provide image information for ons: fetal, abdominal, intra-operative aginal, trans-rectal, neonatal cephalic, aric), peripheral vascular, transesophageal
	•
	•
·	
ype of Use (Select one or both, as applicable)	
Prescription Use (Part 21 CFR 801 Subpart D)	Over-The-Counter Use (21 CFR 801 Subpart C)
PLEASE DO NOT WRITE BELOW THIS LINE - CO	ONTINUE ON A SEPARATE PAGE IF NEEDED.
FOR FDA US	
Concurrence of Center for Devices and Radiological Health (CDRH) (S	Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

> Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Transducer:

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operation	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	† -						<u></u> _			<u> </u>		
Fetal	P	Р	P	Р	Р	2	Р	Р	Р	1	P	5,7,8, 9,10,14
Abdominal	P	Р	Р	Р	P	2,3	Р	Р	Р		P	5,7,8, 9,10,11,12,14,15
Intra-operative (Abdominal)	P	P	P		Р	2	P	P	Р			4,5,7,11
Intra-operative (Neuro)												
Laparoscopic]										
Pediatric	P	P	P	P	P	2,3	P	Р	Р		Р	5,7,8,9,10,12,14,15
Small Organ (Note 1)	P	Р	Р		Р	2	Р	Р	Р		,	4,5,6,7,8,9,10,11,14,15
Neonatal Cephalic	P	Р	P	P	P	3	P	Р	P			
Adult Cephalic	P	P	P	P	P	3	P	P	P			
Trans-rectal	P	P	P		P	2	P	Р	Р		Р	4,5,7,11,12
Trans-vaginal	P	P	P		P	2	P	Р	Р		P	4,5,7,11,12
Trans-urethral	1											
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	Р	Р	Р		Р	2	Р	Р	Р			4,5,6,7,8,9,10,11,14,15
Musculo-skeletal (Superficial)	P	Р	Р		P	2	Р	P	Р			4,5,6,7,8,9,10,11,14,15
Intravascular	İ									<u> </u>		
Other (Specify)	1.											
Cardiac Adult	Р	P	P	P	Р	3	P	Р	P	Р		4,13
Cardiac Pediatric	Р	Р	Р	P	P	3	P	P	P	P		4,13
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	P	Р	P	Р	Р	3	Р					4,13
Intra-cardiac												
Other (Specify)												
Peripheral vessel	P	Р	P	Р	P	2	P	P	P			4,5,6,7,8,9,10,11,14,15
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducers: K123992, K121422 and K103629

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PST-25BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	ie of	Operati	on						,		
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	1	一					<u> </u>					
Fetal		İ	İ					<u> </u>		 		
Abdominal	P	Р	P	Р	P	3	Р	P	P	 		11
Intra-operative (Abdominal)		Ì	<u> </u>									
Intra-operative (Neuro)	Ì		İ									
Laparoscopic	j		†									
Pediatric	P	Р	P	Р	P	3	P	Р	P			
Small Organ (Specify) (1)	Ì		İ					i				
Neonatal Cephalic	P	Р	P	P	P	3	Р	P	P			
Adult Cephalic	P	Р	Р	P	P	3	P	P	P	1		
Trans-rectal			İ									
Trans-vaginal			<u> </u>				•					
Trans-urethral .			İ									
Trans-esoph. (non-Card.)				i				i	···			
Musculo-skeletal (Conventional)								<u> </u>				
Musculo-skeletal (Superficial)				i								7 11.2.1.
Intravascular												
Other (Specify)				T								
Cardiac Adult	P	Р	Р	Р	Р	3	Р	P	P	Р		4.13
Cardiac Pediatric	Р	Р	P	Р	P	3	Р	P	P	P		4,13
Intravascular (Cardiac)				i								.,
Trans-esoph. (Cardiac)				İ			<u>-</u> -			i		
Intra-cardiac						i		i		 		
Other (Specify)			İ					<u> </u>				
Peripheral vessel						· · · · · · · · · · · · · · · · · · ·		 				
Other (Specify)				T		i				-	- 1	

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PST-30BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of (Operation	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	İ		<u> </u>									<u> </u>
Fetal	\Box											i
Abdominal	P	Р	P	Р	P	3	P	P	P			11
Intra-operative (Abdominal)	I											
Intra-operative (Neuro)					•							
Laparoscopic												
Pediatric	P	P	P	P	P	3	P	P	P			
Small Organ (Specify) (1)	Π											
Neonatal Cephalic	P	Р	P	Р	P	3	P	P	Р			
Adult Cephalic	P	Р	P	Р	Р	3	P	P	Р			
Trans-rectal	П						-					
Trans-vaginal												
Trans-urethral												
Trans-esoph. (non-Card.)	Ī											
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)						-						
Intravascular												
Other (Specify)	Π											
Cardiac Adult	Р	Р	P	P	P	3	P	P	Р	P		4,13
Cardiac Pediatric	P	P	P	P	P	3	P	P	P	P		4,13
Intravascular (Cardiac)								1				
Trans-esoph. (Cardiac)		-										
Intra-cardiac					<u> </u>							
Other (Specify)			1									
Peripheral vessel	Π		T									
Other (Specify)	1											

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Note 15 SMI

Transducer: PST-50BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operati	on							· · · · ·	
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic			1	<u> </u>	1			<u> </u>	<u> </u>	1		
Fetal	Ť	<u> </u>	Ť	Ì						<u> </u>		<u> </u>
Abdominal	P	Р	P	P	Р	. 3	Р	Р	Р			11
Intra-operative (Abdominal)	<u> </u>	Ì	İ	İ								
Intra-operative (Neuro)	İ	<u> </u>	<u> </u>					i		<u> </u>		<u> </u>
Laparoscopic	Ì		İ			İ						
Pediatric	P	Р	P	Р	P	3	P	Р	P	 		
Small Organ (Specify) (1)	Ì	İ	İ									
Neonatal Cephalic	P	Р	P	P	P	3	P	Р	P			
Adult Cephalic	Р	Р	Р	P	P	3	P	P	P			
Trans-rectal	Ì		j									
Trans-vaginal	Ì						-					
Trans-urethral	Ì											
Trans-esoph. (non-Card.)		Ì			,							
Musculo-skeletal (Conventional)	1.		İ i							1		
Musculo-skeletal (Superficial)	Ì		Ť					i i				
Intravascular												
Other (Specify)		-										
Cardiac Adult	Р	Р	Р	P	P	3	P	Р	P	Р		4,13
Cardiac Pediatric	Р	P	P	P	Р	3	P	Р	P	P		4,13
Intravascular (Cardiac)			İ İ									-,,.5
Trans-esoph. (Cardiac)												
Intra-cardiac				i i			·			H		
Other (Specify)				i				†				
Peripheral vessel					- PAIR	.						
Other (Specify)				- i								

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost
- Note 15 SMI

Transducer: PST-65AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of	Operati	оп							•	
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic			 	İ				1				
Fetal								1.				
Abdominal	Р	Р	P	P	P	3	P	P	P			11
Intra-operative (Abdominal)		Ī										
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	Р	Р	P	P	Р	3	P	Р	Р			
Small Organ (Specify) (1)							·					
Neonatal Cephalic	Р	Р	P	Р	P	3	Р	P	P			
Adult Cephalic	P	Р	P	Р	P	3	Р	Р	P			
Trans-rectal	<u> </u>	Ī	· -									<u> </u>
Trans-vaginal	İ											
Trans-urethral		1										
Trans-esoph. (non-Card.)	i	Ì	İ	İ								
Musculo-skeletal (Conventional)										i		
Musculo-skeletal (Superficial)	Ť	<u> </u>										
Intravascular												
Other (Specify)	İ		İ	İ		Ì						
Cardiac Adult	Р	P	P	Р	P	3	Р	Р	P	Р		4,13
Cardiac Pediatric	Р	Р	P	P	Р	3	Р	Р	P	Р		4,13
Intravascular (Cardiac)		Ì	T ·	<u> </u>						ĺ		
Trans-esoph. (Cardiac)		<u> </u>	İ									
Intra-cardiac		Ì	Ì	<u> </u>								· · · · · ·
Other (Specify)		Ì	İ	Ì								
Peripheral vessel	İ	<u>. </u>	İ	<u> </u>				<u> </u>		İ		
Other (Specify)		 	 	i 						•		

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Note 15 SMI

Transducer: PVT-375BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	i -	· · · · · · · · · · · · · · · · · · ·	Operati			1 -		1				
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppter	Combined (Specify) *	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	i –		 					1				<u> </u>
Fetal	P	P	Р		Р	2	Р	Р	P	<u> </u>		5, 7
Abdominal	P	Р	P		Р	2	Р	Р	P			5, 7,11,12 ,15
Intra-operative (Abdominal)	Ì	İ	İ			ii				 		,,,,,
Intra-operative (Neuro)	İ.		İ					İ		1		
Laparoscopic			Ì									
Pediatric	P	Р	P		P	2	P	Р	P			5, 7,12,15
Small Organ (Specify) (1)			Ì							<u> </u>		1
Neonatal Cephalic		İ										
Adult Cephalic			İ					i	:			
Trans-rectal												<u>'</u>
Trans-vaginal												
Trans-urethral								<u> </u>				
Trans-esoph. (non-Card.)						,						1
Musculo-skeletal (Conventional)												<u> </u>
Musculo-skeletal (Superficial)												
Intravascular												
Other (Specify)									···			<u> </u>
Cardiac Adult						i]
Cardiac Pediatric												
Intravascular (Cardiac)		-		i i		i						<u> </u>
Trans-esoph. (Cardiac)				i		i						1
Intra-cardiac			İ	ĺ		İ					-,·	
Other (Specify)				i							-	j
Peripheral vessel	İ			i				-				<u> </u>
Other (Specify)	İ			İ		i		i	1			

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PVT-375MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of	Operati	on		,						
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	1	-	1						*	1	<u> </u>	
Fetal	P	P.	P		P	2	Р	P	P		N	5,7,8,9,10
Abdominal	P	Р	P		P	2	Р	P	Ρ.		N	5,7,8,9,10
Intra-operative (Abdominal)		Ī								i		i
Intra-operative (Neuro)						Ī						İ
Laparoscopic	1							ĺ		İ		İ
Pediatric	P	Р	P	Ì '	Р	2	Ρ.	P	P		N	5,7,8,9,10
Small Organ (Specify) (1)	Ť		İ		**						<u> </u>	
Neonatal Cephalic	Ī	i	İ							<u> </u>	<u> </u>	İ
Adult Cephalic										İ		
Trans-rectal	Ť		Ì							<u> </u>		
Trans-vaginal	İ		<u> </u>							İ	i	
Trans-urethral	Ì											1
Trans-esoph. (non-Card.)	İ		İ									
Musculo-skeletal (Conventional)											,	
Musculo-skeletal (Superficial)								Ì	,,			·
Intravascular					-							į
Other (Specify)		Ī										1
Cardiac Adult	1											
Cardiac Pediatric												
Intravascular (Cardiac)	1											
Trans-esoph. (Cardiac)			Ì					Ì				İ
Intra-cardiac			Ī					İ				
Other (Specify)			<u> </u>					İ				<u> </u>
Peripheral vessel			 			İ		İ	······································			İ
Other (Specify)	Ì											

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PVT-382BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operati	on	· ··· · · · ·				 <u>-</u>			
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic		<u> </u>	†	 		-	<u> </u>					
Fetal	P	P	P		Р	2	Р	Р	Р			5, 7
Abdominal	Р	Р	P	1	Р	2	Р	Р	Р			5, 7,12
Intra-operative (Abdominal)	1	Ī						<u> </u>				
Intra-operative (Neuro)				ĺ								<u> </u>
Laparoscopic								İ				
Pediatric	Р	Р	P	<u> </u>	Р	2	Р	Р	P	<u> </u>		5, 7,12
Small Organ (Specify) (1)	İ		<u> </u>	Ì								
Neonatal Cephalic	Ì		İ					i i				
Adult Cephalic			†					1			·	
Trans-rectal		i	İ					 				
Trans-vaginal	İ	·	†									
Trans-urethral			1									
Trans-esoph. (non-Card.)	İ											
Musculo-skeletal (Conventional)			i -					i		<u> </u>		
Musculo-skeletal (Superficial)	İ		<u> </u>					1		1		
Intravascular	İ											
Other (Specify)			†									
Cardiac Adult								 		i		
Cardiac Pediatric												
Intravascular (Cardiac)								i i			<u></u>	
Trans-esoph. (Cardiac)			İ					İ				
Intra-cardiac			Ħ					i			-	
Other (Specify)			İ i					i				
Peripheral vessel												
Other (Specify)			İ					i. i		<u> </u>		

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Note 15 SMI

Transducer: PVT-382MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operati	on		•						
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	1		 		<u></u>			<u> </u>		ļ		
Fetal	P	Р	P		Р	. 2	Р	Р	P	<u> </u>	P	5,7,9
Abdominal	P	P	P		Р	2	Р	P	P		Р	5,7,9
Intra-operative (Abdominal)										Ì		
Intra-operative (Neuro)	-		T									<u> </u>
Laparoscopic												
Pediatric	P	Р	P		Р	2	P	Р	P		Р	5,7,9
Small Organ (Specify) (1)	I	Ī										
Neonatal Cephalic			İ									
Adult Cephalic			Ī									
Trans-rectal	İ		Ì									
Trans-vaginal		İ	1							İ		
Trans-urethral	İ		 			ĺ		i i				
Trans-esoph. (non-Card.)	j		İ									
Musculo-skeletal (Conventional)	T		j									
Musculo-skeletal (Superficial)	Ī							İ				
Intravascular	Ť	İ	İ							İ		
Other (Specify)	 	Ī			· · · · · · · · · · · · · · · · · · ·			Ì				
Cardiae Adult	Ť	Ì	İ									
Cardiac Pediatric	1	Ì	Ī									
Intravascular (Cardiac)	Ì		T			·				İ		
Trans-esoph. (Cardiac)	Ì		T				~~~~			Í		
Intra-cardiac	į.										•	
Other (Specify)	İ	Ì	İ	V					***************************************			
Peripheral vessel	İ	İ	İ					İ				
Other (Specify)	Ì	İ	İ .				·		····			

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD: BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Note 15 SMI

Transducer: PVT-661VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Мос	e of	Operati	on	<u> </u>							
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	<u> </u>		1									<u> </u>
Fetal	İ		i -					 		<u> </u>		
Abdominal			İ									<u> </u>
Intra-operative (Abdominal)	Ì	İ	İ			1				<u> </u>		
Intra-operative (Neuro)	Ì				***************************************	İ		i i				
Laparoscopic		İ	İ									
Pediatric			İ			İ		1				
Small Organ (Specify) (1)	Ì	İ	<u> </u>									
Neonatal Cephalic	İ	Ì	<u> </u>				•					
Adult Cephalic		İ	 				·····					
Trans-rectal	Р	P	P		P	2	P	P	P			4,5,7,11
Trans-vaginal	Р	Р	Р		P	2	Р	P	P			4,5,7,11
Trans-urethral	Ì				-			i				
Trans-esoph. (non-Card.)	i '							İ			•	
Musculo-skeletal (Conventional)					•••			i				
Musculo-skeletal (Superficial)						ĺ				İ		,
Intravascular	Ī			i				İ				
Other (Specify)				j				i				
Cardiac Adult		i						İ				
Cardiac Pediatric	Ì							İ				
Intravascular (Cardiac)					-			i				
Trans-esoph. (Cardiac)				i				İ				
Intra-cardiac				i								
Other (Specify)				i		ĺ						
Peripheral vessel				i		i						
Other (Specify)				i				i i				<u>. </u>

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Note 15 SMI

Transducer: PVT-781VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operati	on								· · · · · · · · · · · · · · · · · · ·
Specific (Tracks 3)	В	М	PWD	ÇWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	 		†	<u> </u>		1						1
Fetal	Ī	Ī	1	Ì						į ·	j	
Abdominal												
Intra-operative (Abdominal)												
Intra-operative (Neuro)												
Laparoscopic				٠.						<u> </u>		
Pediatric			1	<u> </u>								İ
Small Organ (Specify) (1)	Ī		Ì							ļ <u>.</u>		
Neonatal Cephalic			<u> </u>	<u> </u>						Ì		<u> </u>
Adult Cephalic	Ť		İ	<u> </u>		Ī						İ
Trans-rectal	P	Р	P		Р	2	Р	P	P	İ		4,5,7,11,12
Trans-vaginal	P	P	P	Ī	Р	2	Р	Р	P			4,5,7,11,12
Trans-urethral	İ		1	İ								
Trans-esoph. (non-Card.)			"									
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)			1		·							
Intravascular	Ì											
Other (Specify)	1											
Cardiac Adult	T	Ì										
Cardiac Pediatric												
Intravascular (Cardiac)	1	ļ										
Trans-esoph. (Cardiac)			T	T						T		
Intra-cardiac	1											
Other (Specify)	T		T	Ī .					_		,	
Peripheral vessel												
Other (Specify)	-	Ι.		l								1

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure -

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Note 15 SMI

Transducer: PVT-674BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of	Operati	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	<u> </u>		†							1	<u> </u>	<u> </u>
Fetal	P	P	Р		Р	2	P	P	Р	į ·		5,7,14
Abdominal	P	Р	P		Р	2	Р	Р	P			5,7,14
Intra-operative (Abdominal)	,			i				i i		İ		
Intra-operative (Neuro)		İ	1					İ		i		i
Laparoscopic	T											<u> </u>
Pediatric	P	P	P	İ	Р	2	Р	Р	Р			5,7,14
Small Organ (Specify) (1)	T									İ		
Neonatal Cephalic	T		Ì							Ϊ.		İ
Adult Cephalic	1 -		Ť					İ				İ
Trans-rectal	Ī											
Trans-vaginal	1		<u> </u>					İ	•	İ		i
Trans-urethral			Ì									
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)	İ		İ				-	i				İ
Intravascular	i .			-				i i		İ		
Other (Specify)								İ	•	İ		i
Cardiac Adult	Ì							i i				
Cardiac Pediatric								i		İ		
Intravascular (Cardiac)										İ		
Trans-esoph. (Cardiac)								i i				
Intra-cardiac								i i	-			
Other (Specify)								<u> </u>				
Peripheral vessel		·				İ		<u> </u>		İ		
Other (Specify)						j		i i		<u> </u>		

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PVT-675MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of (Operati	on								
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	-	-	 		<u> </u>					<u> </u>	<u> </u>	1
Fetal	P	Р	P		Р	2	Р	P	Р		P	5,7,8,9,10
Abdominal	P	Р	P		P	2	Р	P	P		P	5,7,8,9,10
Intra-operative (Abdominal)	Ť		Ì	Ì							Ì	
Intra-operative (Neuro)			1									Í
Laparoscopic	1	<u> </u>	İ							İ		Ì
Pediatric	P	P	P		Р	2	Р	Р	Р		P	5,7,8,9,10
Small Organ (Specify) (1)	Ì	Ì	İ									İ
Neonatal Cephalic	Ì		İ	<u> </u>			· ·			<u> </u>		
Adult Cephalic	T			Ì.								
Trans-rectal	Ī		1							İ		j
Trans-vaginal			Ī.					İ				
Trans-urethral			Ī									
Trans-esoph. (non-Card.)			Ī	İ						Ì		
Musculo-skeletal (Conventional)					:							
Musculo-skeletal (Superficial)	T		Ì					<u> </u>		İ		Í
Intravascular										İ		
Other (Specify)			Ī									
Cardiac Adult												İ
Cardiac Pediatric												
Intravascular (Cardiac)	1											
Trans-esoph. (Cardiac)										Γ		1
Intra-cardiac			 									
Other (Specify)												į
Peripheral vessel	:									Ì		
Other (Specify)	Ì					1						

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PVT-681MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operati	on							•	
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	 	Ħ			<u> </u>			 				1
Fetal		Ī	İ		<u> </u>							1
Abdominal			Ì							<u> </u>		1
Intra-operative (Abdominal)		İ		·						1		İ
Intra-operative (Neuro)	İ	Ì										
Laparoscopic	1	Ì	 	<u> </u>			·	† — i		<u> </u>		i –
Pediatric	Ť	Ì	İ							i .		†
Small Organ (Specify) (1)	Ť		j –						· <u>-</u>			1
Neonatal Cephalic	1	İ							•			
Adult Cephalic	İ	 										†
Trans-rectal	P	P	Р		P	2	P	Р	P		P	4,5,7,9,11
Trans-vaginal	P	P	Р		P	2	Р	P	P		P	4,5,7,9,11
Trans-urethral	Ť		<u> </u>			ii		1		Ì		
Trans-esoph. (non-Card.)		<u> </u>	<u> </u>									<u>, </u>
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)	1		İ					i			!	
Intravascular	T											
Other (Specify)	İ							i i				
Cardiac Adult	1							İ				
Cardiac Pediatric								i i				
Intravascular (Cardiac)								i i				İ
Trans-esoph. (Cardiac)	Ť.	İ						i i				
Intra-cardiac							-	. 1				<u> </u>
Other (Specify)								i i				i ·
Peripheral vessel												i i
Other (Specify)								j				

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PVT-712BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of (Operation	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	<u> </u>	 	 	1								
Fetal	T											
Abdominal	P	P	P		P	2	Р	P	Р			5,7
Intra-operative (Abdominal)	1											
Intra-operative (Neuro)										Ì		
Laparoscopic	T	Ī								·		
Pediatric	P	P	Р		Р	2	Р	Р	Р			5,7
Small Organ (Specify) (1)	Ī			<u> </u>		-						Ì
Neonatal Cephalic	P	P	P	<u> </u>	P	2	Р	Р	P			5,7
Adult Cephalic	1											
Trans-rectal	1											
Trans-vaginal	Ī											
Trans-urethral	1				ŀ							1
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)	T											!
Intravascular			T								•	
Other (Specify)			T									
Cardiac Adult			T									
Cardiac Pediatric												
Intravascular (Cardiac)	1											
Trans-esoph. (Cardiac)	T				į							
Intra-cardiac			Ţ	T	-					Ţ		
Other (Specify)	1		1	-	-		[ſ
Peripheral vessel	T		T]	T			·			
Other (Specify)	1		T	<u> </u>	<u> </u>							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PVT-745BTF

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of (Operati	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	1		1		<u> </u>	<u> </u>	<u>_</u>			†		<u> </u>
Fetal			İ		<u>-</u>	<u> </u>				<u> </u>		<u> </u>
Abdominal	P	Р	Р		Р	2	P	Р	Р			5,7
Intra-operative (Abdominal)	Р	Р	P		Р	2	Р	Р	P			5.7
Intra-operative (Neuro)												
Laparoscopic	j "	İ	Ī		-							
Pediatric												<u> </u>
Small Organ (Specify) (1)		<u> </u>	ĺ									
Neonatal Cephalic	1	<u> </u>						İ				
Adult Cephalic												
Trans-rectal	Ì							i -				
Trans-vaginal								 		! 		
Trans-urethral			<u> </u>					<u> </u>				
Trans-esoph. (non-Card.)	<u> </u>											
Musculo-skeletal (Conventional)									· · · · · · · · · · · · · · · · · · ·			
Musculo-skeletal (Superficial)								i i				
Intravascular									<u>-</u>			
Other (Specify)												
Cardiac Adult							·,					
Cardiac Pediatric												
Intravascular (Cardiac)				i		İ		i i				
Trans-esoph. (Cardiac)				j								
Intra-cardiac				i				İ		<u> </u>		,,,
Other (Specify)			i	i	*-	İ		j				
Peripheral vessel				i	•			İ		 		
Other (Specify)	i		i i	j								

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PVT-745BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of	Operati	on								
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	тні	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic		i	1									
Fetal ·												
Abdominal	P	Р	P	Ì	P	2	P	P	P			5,7
Intra-operative (Abdominal)	P	Р	Р		P	2	P	P	Р	Ī		5,7
Intra-operative (Neuro)			Ť							ļ		
Laparoscopic	1											
Pediatric	1	i –	Ì									
Small Organ (Specify) (1)	T		1									
Neonatal Cephalic	Ť	ĺ .	Ť –							Ì		
Adult Cephalic	1									İ		
Trans-rectal	1		Ì						-			
Trans-vaginal	Ť		Ì							İ		
Trans-urethral			Í									
Trans-esoph. (non-Card.)		Ť	T									
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)	T											
Intravascular			ĺ			1						
Other (Specify)			Ī									
Cardiac Adult												
Cardiac Pediatric	j		İ									
Intravascular (Cardiac)												1
Trans-esoph. (Cardiac)			1.									
Intra-cardiac	İ											
Other (Specify)						<u> </u>		[
Peripheral vessel			1							<u> </u>		
Other (Specify)	1	Ì	1	İ								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PVT-745BTV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of	Operati	on								· · · · · · · · · · · · · · · · · · ·
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	†		1	Ī	<u> </u>					1		<u> </u>
Fetal]										İ
Abdominal	P	Р	P		Р	2	Р	Р	P			5,7
Intra-operative (Abdominal)	P	Р	P	Ì	P	2	P	Р	P			5,7
Intra-operative (Neuro)			Ī									<u>† </u>
Laparoscopic												i
Pediatric			<u> </u>							i i		
Small Organ (Specify) (1)									· · · · · · · · · · · · · · · · · · ·			
Neonatal Cephalic	Ţ.,		İ					 		<u> </u>		
Adult Cephalic			İ		-							<u>,</u>
Trans-rectal	İ		i i	i				1				
Trans-vaginal	<u> </u>											
Trans-urethral								1			<u></u>	
Trans-esoph. (non-Card.)	i		İ					 				
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)	Ì		<u> </u>	<u> </u>				i i				
Intravascular	i		i :					 				
Other (Specify)			<u> </u>									
Cardiac Adult				i				i i				<u></u>
Cardiac Pediatric								- 				
Intravascular (Cardiac)	İ		<u> </u>					i				
Trans-esoph. (Cardiac)	İ			<u> </u>				<u> </u>		<u> </u>		
Intra-cardiac			<u> </u>									
Other (Specify)			İ									
Peripheral vessel	T		İ									
Other (Specify)	İ		i i					 				

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PVT-770RT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operati-	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	<u> </u>	İ	<u> </u>									1
Fetal	1	Ī										
Abdominal	<u> </u>											
Intra-operative (Abdominal)	Ī	Ì					····					
Intra-operative (Neuro)	T	Ī								İ		
Laparoscopic	Ī	<u> </u>	7							Ì		
Pediatric	<u> </u>	Ì	Ī	<u> </u>								· ·
Small Organ (Specify) (1)	Ì	Ť								ĺ		
Neonatal Cephalic	İ	Ť –	Ī	ļ								
Adult Cephalic	Ī	Ť	1	l								
Trans-rectal	P	P	P		Р	2	P	Р	P			4,5,7,11
Trans-vaginal	P	P	P		Р	2	Р	Р	P	İ		4,5,7,11
Trans-urethral		İ										
Trans-esoph. (non-Card.)		1										
Musculo-skeletal (Conventional)												<u> </u>
Musculo-skeletal (Superficial)		İ		İ								
Intravascular		İ	İ						-			
Other (Specify)		Ì	İ									1
Cardiac Adult												
Cardiac Pediatric	Í	Ì				I						<u> </u>
Intravascular (Cardiac)			T									
Trans-esoph. (Cardiac)		Ì	Ì	İ								
Intra-cardiac			T	<u> </u>								
Other (Specify)												
Peripheral vessel		Ť –										
Other (Specify)	<u> </u>	İ										

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PLT-604AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of	Operati	on								.=
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	 		 	<u> </u>				<u> </u>				<u> </u>
Fetal	Í		1	İ								<u> </u>
Abdominal								İ				 -
Intra-operative (Abdominal)		İ	İ									
Intra-operative (Neuro)	Ť		İ	İ				 				,
Laparoscopic		İ	Í					İ				
Pediatric			İ									
Small Organ (Specify) (1)	P	Р	Р		P	2	Р	Р	P			5,7
Neonatal Cephalic	Ì		İ					i i				
Adult Cephalic		ĺ	İ					İ				
Trans-rectal	Ť	Ì	Ì				••					
Trans-vaginal	· [Í						
Trans-urethral			i			i i		<u> </u>				
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	Р	Р		P	2	P	P	Р			5,7
Musculo-skeletal (Superficial)	Р	P	Р		P	2	P	Р	P			5,7
Intravascular								-				
Other (Specify)		-										
Cardiac Adult												
Cardiac Pediatric				i								
Intravascular (Cardiac)				İ								
Trans-esoph. (Cardiac)				İ						i		
Intra-cardiac				·i	•					Ì		
Other (Specify)				İ						i		<u>.</u>
Peripheral vessel	Р	P	Р		P	2	P	P	P		j	5,7
Other (Specify)			m	i				 i		i	<u> </u>	

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PLT-704AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Moc	le of	Operati	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	Ť		<u> </u>		·					<u> </u>		<u> </u>
Fetal									,			
Abdominal										Ì		<u> </u>
Intra-operative (Abdominal)								İ				<u> </u>
Intra-operative (Neuro)												i i
Laparoscopic									:	ļ		
Pediatric									-			Ì
Small Organ (Specify) (1)	P	Р	P		P	2	P	P	P			5,7
Neonatal Cephalic												
Adult Cephalic												İ
Trans-rectal	T											j
Trans-vaginal			Ì					İ				
Trans-urethral			Ì									
Trans-esoph. (non-Card.)								İ				
Musculo-skeletal (Conventional)	P	Р	Р		P	2	P	P	Р	·		5,7
Musculo-skeletal (Superficial)	P	P	Р		Р	2	P	Р	P			5,7
Intravascular												
Other (Specify)								İ				
Cardiac Adult					·			İ				
Cardiac Pediatric								i i				
Intravascular (Cardiac)						i						
Trans-esoph. (Cardiac)												
Intra-cardiac												
Other (Specify)	1							İ				
Peripheral vessel	P	P	Р		P	2	P	Р	P			5.7
Other (Specify)	1	<u> </u>		ĺ				i i				

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PLT-704SBT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific	В		Operation PWD		Cala	Combined	77111	In				
(Tracks 3)	В	1	PWD	СМВ	Color Doppler	(Specify)	IHI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	1-	 							•		·	<u> </u>
Fetal	Ī	İ							. ,	<u> </u>		
Abdominal								†				<u> </u>
Intra-operative (Abdominal)												i
Intra-operative (Neuro)											<u> </u>	
Laparoscopic	Ť							İ				
Pediatric												
Small Organ (Specify) (1)	Р	Р	Р		Р	2	P	P	P			5,7,14,13
Neonatal Cephalic						i i						
Adult Cephalic												 -
Trans-rectal								İ			*	
Trans-vaginal	1	Ī						İ				
Trans-urethral	1											
Trans-esoph. (non-Card.)	Ī					<u> </u>		İ				<u> </u>
Musculo-skeletal (Conventional)	P	Р	Р		Р	2	Р	Р	P			5,7,14,15
Musculo-skeletal (Superficial)	P	Р	Р		P	2	Р	P	P			5,7,14,15
Intravascular												
Other (Specify)			i i				-					<u> </u>
Cardiac Adult					**	i				· · · · i		
Cardiac Pediatric								i				<u> </u>
Intravascular (Cardiac)												İ
Trans-esoph. (Cardiac)			T	İ		-		İ		1		İ
Intra-cardiac												i -
Other (Specify)												İ
Peripheral vessel	P	Р	Р		P	2	Р	Р	P	1		5,7,14,15
Other (Specify)			1	i		i			·			

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Note15 SMI

Transducer: PLT-705BTF

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of (Operation	on	·							
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	Ť		1						 			
Fetal		1										
Abdominal	P	Р	P		P	2	Р	Р	Р			5.7
Intra-operative (Abdominal)	P	P	P		P	2	P	Р	P			5,7
Intra-operative (Neuro)	T										***	
Laparoscopic												
Pediatric								Ì				
Small Organ (Specify) (1)	İ											
Neonatal Cephalic	ì				-							
Adult Cephalic	Ī											
Trans-rectal								 				
Trans-vaginal	Ì		İ					İ				
Trans-urethral	İ											
Trans-esoph. (non-Card.)	Ť		İ					İ				
Musculo-skeletal (Conventional)											•	
Musculo-skeletal (Superficial)	Ī							İ				
Intravascular	T							İ				
Other (Specify)												
Cardiac Adult		i						İ				
Cardiac Pediatric	T										:	
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)	1	Ī										
Intra-cardiac						j						
Other (Specify)	1							İ				
Peripheral vessel	<u> </u>							İ				
Other (Specify)			<u> </u>								· · · · · · · · · · · · · · · · · · ·	

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K123992

- Note 1 Small organ includes thyroid, breast and testicle.
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost
- Note 15 SMI

Transducer: PVT-705BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
					zoppic.	*		1.0"		20		Inotel
Ophthalmic												
Fetal					<u> </u>					İ		i
Abdominal	P	P	P		P	'2	Р	P	Р	İ		5,7
Intra-operative (Abdominal)	P	Р	P		Р	2	P	Р	P			5,7
Intra-operative (Neuro)												
Laparoscopic												
Pediatric								i i				
Small Organ (Specify) (1)			T .							<u> </u>		•
Neonatal Cephalic	T					i i		i i				
Adult Cephalic								i.			-	
Trans-rectal						i i		i			•	
Trans-vaginal						Ì						<u> </u>
Trans-urethral			T									
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)								i				
Intravascular			•					i				:
Other (Specify)				•				i				
Cardiac Adult												
Cardiac Pediatric	ĺ		Ì	i				<u> </u>				
Intravascular (Cardiac)				i						 		
Trans-esoph. (Cardiac)	T		<u> </u>	i								
Intra-cardiac				i						i		
Other (Specify)	1		İ		-						-	
Peripheral vessel	Ì							ii				
Other (Specify)				-		-						

N = new indication; P = previously cleared by FDA; E = added under this appendix

Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PLT-805AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operati	on				······································		 -		
Specific (Tracks 3)	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	 	 	†	İ					· · · · · · · · · · · · · · · · · · ·	<u> </u>		
Fetal												1
Abdominal	T		1									
Intra-operative (Abdominal)												i
Intra-operative (Neuro)	Π		T									
Laparoscopic		-						Ì				
Pediatric			T									İ
Small Organ (Specify) (1)	Р	P	P		Р	2	P	Р	P			5,6,7,11
Neonatal Cephalic								i i				
Adult Cephalic		İ						İ				
Trans-rectal			i									İ
Trans-vaginal			İ									
Trans-urethral			İ									
Trans-esoph. (non-Card.)	ĺ		Ì									
Musculo-skeletal (Conventional)	P	P	P		Р	2	Р	Р	P			5,6,7,11
Musculo-skeletal (Superficial)	Р	Р	P		Р	2	P	P	P			5,6,7,11
Intravascular			<u> </u>									Ì
Other (Specify)	Ì	Ì				İ						i
Cardiac Adult	Ī	Ì										İ
Cardiac Pediatric						İ						i
Intravascular (Cardiac)												İ
Trans-esoph. (Cardiac)			1			i						
Intra-cardiac .						ļ.		i				Ī
Other (Specify)			T			1						
Peripheral vessel	Р	P	P		Р	2	Р	Р	Р			5,6,7,11
Other (Specify)						i i						<u> </u>

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PLT-1005BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Specific	В	M	PWD	CWD	Color	Combined	THI	Dynamic	Power	CHI	4D	Other
(Tracks 3)					Doppler	(Specify)		Flow	10	2D	10	[Note]
Ophthalmic	<u> </u>		†			1	-				<u> </u>	<u>!</u>
Fetal										 		<u> </u>
Abdominal									<u> </u>	<u> </u>	i	
Intra-operative (Abdominal)					·						<u></u>	
Intra-operative (Neuro)		Ī									<u> </u>	
Laparoscopic		<u> </u>										
Pediatric	Í									 		<u> </u>
Small Organ (Specify) (1)	P	Р	P		Р	2	P	Р	P			5,6,7,11,14,15
Neonatal Cephalic	İ	i										T ,
Adult Cephalic	İ	<u> </u>							·			
Trans-rectal								<u> </u>				1
Trans-vaginal	Ì											-
Trans-urethral		Ì										<u> </u>
Trans-esoph. (non-Card.)	<u> </u>							<u>. </u>				<u> </u>
Musculo-skeletal	Р	Р	Р		P	2						
(Conventional)		Р	P		P	2	Р	P	P			5,6,7,11,14,15
Musculo-skeletal (Superficial)	Р	P	Р		P	2	Р	Р	P			5,6,7,11,14,15
Intravascular				.								
Other (Specify)				İ				i				
Cardiac Adult				'								
Cardiac Pediatric												
Intravascular (Cardiac)									-			
Trans-esoph. (Cardiac)				i				i				
Intra-cardiac												
Other (Specify)		-		Ì								
Peripheral vessel	Р	P	P	Í	Р	2	P	Р	Р			5,6,7.11,14,15
Other (Specify)										i		

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Note 15 SMI

Transducer: PLT-1202S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operati	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic			ļ <u>-</u>									
Fetal									,			
Abdominal												
Intra-operative (Abdominal)	P	P	Р		P	2	Р		P			4,5,11
Intra-operative (Neuro)												
Laparoscopic												
Pediatric	ĺ		ļ									
Small Organ (Specify) (1)	Р	P	Р		P	2 .	Р		P			4,5,11
Neonatal Cephalic	T		ĺ									
Adult Cephalic	Ī	Ì	Ī	Ī								
Trans-rectal		İ		<u> </u>								
Trans-vaginal			T									
Trans-urethral												
Trans-esoph. (non-Card.)			Ī									
Musculo-skeletal (Conventional)	P	P	P		Р	2	Р		P			4,5,11
Musculo-skeletal (Superficial)	Р	Р	P		Р	2	Р		P			4,5,11
Intravascular			T									
Other (Specify)	Г											
Cardiac Adult												
Cardiac Pediatric												
Intravascular (Cardiac)												
Trans-esoph. (Cardiac)			T	Ī						-		
Intra-cardiac			T									
Other (Specify)				ļ								
Peripheral vessel	P	Р	P		P	2	Р		Р			4,5,11
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Note 15 SMI

Transducer: PLT-1204BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of (Operatio	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	+				<u> </u>	1						1
Fetal												
Abdominal												Ī
Intra-operative (Abdominal)						1						1
Intra-operative (Neuro)	Ì											1
Laparoscopic		Ī										1
Pediatric	T	Ì										i i
Small Organ (Specify) (1)	P	Р	Р		P	2	P	Р	P	,		4,5,6,7,11 15,
Neonatal Cephalic	†							i i				1
Adult Cephalic	1	1			-		-					
Trans-rectal	1.							i i				
Trans-vaginal	İ	<u> </u>						<u> </u>				1
Trans-urethral	Ť							İ				
Trans-esoph. (non-Card.)	Ī							İ				<u> </u>
Musculo-skeletal (Conventional)	P	P	Р		Р	2	P	Р	P			4,5,6,7,11 15
Musculo-skeletal (Superficial)	P	P	Р		Р	2	P	Р	P		····	4,5,6,7,11. 15
Intravascular				-				i				
Other (Specify)								İ			•	<u> </u>
Cardiac Adult												
Cardiac Pediatric				i				i ·			·····	†
Intravascular (Cardiac)												<u> </u>
Trans-esoph. (Cardiac)	Ì							i		İ		1
Intra-cardiac	T			j				i i		i		<u> </u>
Other (Specify)			ΓÌ	i				İ				i
Peripheral vessel	Р	P	Р		P	2	Р	Р	Р			4,5,6,7,11, 15
Other (Specify)				i				İ				i

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

- Note 1 Small-organ-includes thyroid, breast and testicle:
- Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
- Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD
- Note 4 TDI
- Note 5 ApliPure
- Note 6 MicroPure
- Note 7 Precision Imaging
- Note 8 STIC
- Note 9 3D Color (Volume Color)
- Note 10 STIC Color
- Note 11 Elastography
- Note 12 Fusion
- Note 13 2D WMT
- Note 14 Boost
- Note 15 SMI

System: <u>Aplio 500 300 V4.0</u>. Transducer: <u>PLT-1204BX</u>

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operati	on							-	
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic			1	<u> </u>								
Fetal												
Abdominal		,										
Intra-operative (Abdominal)	į											İ
Intra-operative (Neuro)		-		ĺ								İ
Laparoscopic			Ì	İ				<u> </u>				İ
Pediatric	1	<u> </u>						İ				i
Small Organ (Specify) (1)	P	P	P	Ì	P	2	P	P	P			5,7
Neonatal Cephalic			Ī					İ				
Adult Cephalic		Ì		Ì								
Trans-rectal	ĺ		1					į i				İ
Trans-vaginal											_	
Trans-urethral	Ì											İ
Trans-esoph. (non-Card.)						Í						<u> </u>
Musculo-skeletal (Conventional)	Р	Р	P		P	2	Р	P	Р			5,7
Musculo-skeletal (Superficial)	P	P	Р		P	2	Р	Р	Р			5.7
Intravascular												
Other (Specify)												
Cardiac Adult												
Cardiac Pediatric	Ī				1						·	
Intravascular (Cardiac)								<u> </u>				<u> </u>
Trans-esoph. (Cardiac)												
Intra-cardiac	7											ļ
Other (Specify)												
Peripheral vessel	P	P	Р		P	2	Р	Р	P			5,7
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF: BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PLT-1204MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operati	on _	-							
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	-		1									1
Fetal		1						İ				i
Abdominal		Ī										†
Intra-operative (Abdominal)	1	Ī										T
Intra-operative (Neuro)		Ì	İ	, ·		İ		1		·		
Laparoscopic		Ì	İ				,	İ	· · · · · · · · · · · · · · · · · · ·			1
Pediatric		İ	Ì						7			†
Small Organ (Specify) (1)	P	Р	P		Р	2	Р	Р	P		P	5,7,8,9,10
Neonatal Cephalic		Ì	j -									-,,,,,,,,,
Adult Cephalic	Ţ	<u> </u>						İ				
Trans-rectal	Ť							İ				<u> </u>
Trans-vaginal								İ				
Trans-urethral												<u> </u>
Trans-esoph. (non-Card.)												
Musculo-skeletal (Conventional)	P	Р	Р		Р	2	P	P.	Р		P	5.7,8,9,10
Musculo-skeletal (Superficial)	P	P	Р		P	2	P	P	Р		P	5,7,8,9,10
Intravascular						i		i				1
Other (Specify)	1						•		-		-	1
Cardiac Adult	T				:							<u> </u>
Cardiac Pediatric	T	<u> </u>		Ì								i
Intravascular (Cardiac)								i				<u> </u>
Trans-esoph. (Cardiac)						ĺ		İ				<u> </u>
Intra-cardiac										.		
Other (Specify)										<u>†</u>		
Peripheral vessel	Р	P	P		Р	2	P	Р	P		P	5,7,8,9,10
Other (Specify)			İ	-					*****		· · ·	, . , . , . ,

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PET-508MA

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	e of 0	Operati	on								
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	<u> </u>	<u> </u>	 									
Fetal	1		İ									<u> </u>
Abdominal	,											
Intra-operative (Abdominal)			i –									
Intra-operative (Neuro)	1		İ									
Laparoscopic				Ì				ĺ				
Pediatric	T	Ī	Ī									İ
Small Organ (Specify) (1)												
Neonatal Cephalic												
Adult Cephalic												Ì
Trans-rectal	Ì						· 	İ				
Trans-vaginal	1											
Trans-urethral												
Trans-esoph. (non-Card.)	T							İ				
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)								İ				
Intravascular	İ											·
Other (Specify)								İ				
Cardiac Adult								<u> </u>				
Cardiac Pediatric			<u> </u>				,					
Intravascular (Cardiac)								l i				
Trans-esoph. (Cardiac)	Р	p	Р	Р	P	3	P	İ				4,13
Intra-cardiac								i i				
Other (Specify)			1					i i				
Peripheral vessel							i	İ				
Other (Specify)								Ì				

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PET-510MB

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Moc	le of (Operati	on								-
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic	İ		†		•							
Fetal												
Abdominal												
Intra-operative (Abdominal)			1									
Intra-operative (Neuro)	T		İ					ĺ				
Laparoscopic												
Pediatric			T -									
Small Organ (Specify) (1)												
Neonatal Cephalic			Ī			Ì						
Adult Cephalic												
Trans-rectal												
Trans-vaginal					· · · · · · · · · · · · · · · · · · ·			i i				
Trans-urethral	İ	i				1						
Trans-esoph. (non-Card.)						· ·						
Musculo-skeletal (Conventional)			1		· · · · ·							
Musculo-skeletal (Superficial)			i					<u> </u>				
Intravascular												
Other (Specify)	1											
Cardiac Adult												
Cardiac Pediatric	T											
Intravascular (Cardiac)					-							
Trans-esoph. (Cardiac)	P	P	P	Р	P	3	P					4,13
Intra-cardiac												
Other (Specify)												
Peripheral vessel	1								•			
Other (Specify)												

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PET-512MC

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mod	le of	Operati	on		·						
Specific (Tracks 3)	В	M	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]
Ophthalmic			 							<u> </u>		<u> </u>
Fetal								<u> </u>		i		†
Abdominal										<u> </u>		
Intra-operative (Abdominal)					, .				1PJ_1			
Intra-operative (Neuro)	1							i i				
Laparoscopic	1							i i				i
Pediatric								<u>i</u>				
Small Organ (Specify) (1)	1	1	1									<u> </u>
Neonatal Cephalic												
Adult Cephalic			i					İ				
Trans-rectal												
Trans-vaginal								İ				İ .
Trans-urethral												
Trans-esoph. (non-Card.)	Ī					,			•			<u> </u>
Musculo-skeletal (Conventional)												
Musculo-skeletal (Superficial)		_						i i				
Intravascular	1								····			
Other (Specify)	1							i				
Cardiac Adult	Ì							i				<u> </u>
Cardiac Pediatric	İ							<u> </u>				j
Intravascular (Cardiac)								i				<u> </u>
Trans-esoph. (Cardiac)	P	Р	Р	Р	Р	3	P					4,13
Intra-cardiac				i				İ			· .	<u> </u>
Other (Specify)				Ì	•			İ				
Peripheral vessel				İ		i		i				i
Other (Specify)				i		i						

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: 103629

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PC-20M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation												
	В	М	PWD	CWD	Color Doppler	Combined (Specify)	THI	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic	 	 			! 		,					i İ	
Fetal	1.	i —		<u> </u>					712			<u> </u>	
Abdominal				<u> </u>	<u> </u>	İ		İ					
Intra-operative (Abdominal)		<u> </u>		Ì	i								
Intra-operative (Neuro)									•				
Laparoscopic	i -												
Pediatric	1		İ										
Small Organ (Specify) (1)			Ť										
Neonatal Cephalic							-	i					
Adult Cephalic	1		İ	<u> </u>					•				
Trans-rectal	Î		 	Ì									
Trans-vaginal			İ						-				
Trans-urethral	T	Ī	† 										
Trans-esoph. (non-Card.)		<u> </u>				İ		Ì					
Musculo-skeletal (Conventional)													
Musculo-skeletal (Superficial)	Ť ·		į			i		i i					
Intravascular	1	ļ ——	İ					Ì					
Other (Specify)	<u> </u>		İ			İ		İ					
Cardiac Adult	1		İ	Р		İ					· · · · · · · · · · · · · · · · · · ·		
Cardiac Pediatric	1	Ĭ		Р		İ		i .					
Intravascular (Cardiac)													
Trans-esoph. (Cardiac)	1												
Intra-cardiac	Ī							İ					
Other (Specify)	T												
Peripheral vessel			Ī	Р				j					
Other (Specify)								<u> </u>					

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD: BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost

Transducer: PC-50M

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Specific (Tracks 3)	Mode of Operation												
	В	M	PWD	CWD	Color Doppler	Combined (Specify)	ТНІ	Dynamic Flow	Power	CHI 2D	4D	Other [Note]	
Ophthalmic	İ	 	†			1		1		1	<u> </u>		
Fetal	T	T -				j —			<u> </u>			 	
Abdominal												İ	
Intra-operative (Abdominal)	Ì		Ì					<u> </u>				<u> </u>	
Intra-operative (Neuro)			İ			·	· · · · · · · · · · · · · · · · · · ·	1				1	
Laparoscopic			İ									 	
Pediatric	T					i			~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~ ~			 	
Small Organ (Specify) (1)			Ì				· · · ·					i —	
Neonatal Cephalic										i		 	
Adult Cephalic								İ				<u> </u>	
Trans-rectal	İ					<u> </u>		İ			• • • • • • • • • • • • • • • • • • • •	i	
Trans-vaginal	Ť.	_	Ì										
Trans-urethral	İ					i i		i i				1	
Trans-esoph. (non-Card.)								İ			•		
Musculo-skeletal (Conventional)									:				
Musculo-skeletal (Superficial)												<u> </u>	
Intravascular								İ					
Other (Specify)								İ					
Cardiac Adult				Р									
Cardiac Pediatric				P	· · ·			Ì					
Intravascular (Cardiac)				İ				i					
Trans-esoph. (Cardiac)				İ									
Intra-cardiac	1			Ì		İ		Ì					
Other (Specify)				İ		i				i i			
Peripheral vessel				Р									
Other (Specify)			<u> </u>	İ	•			•					

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K123992

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Note 14 Boost